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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,705	06/08/2001	Xianqiang Li	26757-704	1050

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/07/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/877,705

Applicant(s)

LI, XIANQIANG

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it is too long and uses phraseology often used in patent claims e.g., "comprising". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of **50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (typographical such as "agaraose" at page 24, line 15; grammatical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed method for screening for transcription factor modulators is not adequately described in the disclosure. The disclosure does not describe a single or any transcription factors(tf) modulators that has been identified or screened by the method. Screening a compound (modulators, in the instant case) normally entails or requires screening a library. However, the specification provides a library of transcription factor probes, not a library of modulators. The Examples in the disclosure does not provide guidance or direction as to the method of modulators screening. The methodology does not present

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any experiments as to how the library, if any, modulators are made or how screening is achieved for said modulators. The Examples present only results of an alleged experiment. A detail method of the experiments like the conditions, the library and the materials for the methods are not positively recited. Absent any description and direction, the complex determination of the numerous different variables of the invention is not adequately described. As recognized by applicants, each tf probe has binding specificity for a single transcription factor or family of transcription factors. Note further applicant numerous attempts to employ several methods for the isolation of the tf-probe complex. Some of which failed to provide a sufficient yield of probe-transcription factor complexes from the sample. For example, applicants attempted to isolate probe-transcription factor complexes by performing an ammonia precipitation. Applicants also attempted to isolate probe-transcription factor complexes by passing the sample through a nitrocellulose filter, the filter serving to immobilize proteins while allowing DNA that is not bound to protein to pass through the filter. Unfortunately, neither of these approaches provided a satisfactory yield of complexes for further characterization of the isolated probes. Applicant also attempted to isolate probe-transcription factor complexes by using acrylamide gel

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electrophoresis. Unfortunately, this approach also did not provide a satisfactory yield of complexes. After several attempts Applicant successfully isolated probe-transcription factor complexes from the sample using agarose gel electrophoresis. [The separation method is but one of the numerous undefined variables of the claimed]. Thus, the generalized statements in the specification are not an adequate written description of the invention. There is not a single modulator that is described that influences a transcription factor activity, let alone, modulators that influence multiple different transcription factors at the same time.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 1 is unclear as to whether a modulator or a transcription factor probes is being screened. The preamble recites for screening a modulator. But the body recites for a

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library of tf probes. As a skilled in the art knows, screening is done with a library. It recites for identifying tf probes using an array. Furthermore, the body of the claim recites for comparison of the different activated tf from the samples. The claims appear to cover several embodiments of the invention. The used of different terminologies to mean the same thing provides for confusion and ambiguity. For example "test samples" and "samples of cells"; "tf" and **activated** tf"; "DNA **trancription probes**", DNA **probes**" and "probes". The terms "modulators" and "capable" connotes uncertainty as to whether binding occurs or as to the kind of modulation that is done, especially in the absence of positive description or showing in the specification.

B). Claims 2-7 are indefinite in the recitation of 1-5% of the length of the recognition sequences. It is not clear as to the standard or maximum length of the recognition sequence by which the percentage is based upon. Also, it is not clear as to the other different lengths included in the library. The preamble "A" should be amended to -The---since there is proper antecedent support in the base claim for the methods in each of the claims.

C). Claims 8-9 are indefinite as to the library having between 20 and 40 base pairs in length i.e., whether the

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libraries cover different recognition sequences of varying kind and length of sequences or of the same lengths.

D). Claims 10-15 are indefinite as to the metes and bounds of "at least" different DNA recognition sequences i.e., the maximum kind and length of DNA sequences contained in the library.

E). "The binding regions" in claim 17 lack antecedent basis of support from the base claim. The metes and bounds of "a portion" of the recognition sequence is not clearly set forth in the claims or specification. "Compliment" is misspelled in this claim and specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Weissman et al (US 6,066,452).

Weismann et al discloses at col. 2, line 20 up to col.3, line 25 a method for isolating DNA-binding proteins, comprising:

(a) mixing a set of oligonucleotide duplexes comprising 5' and

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3' sequences that will hybridize to primers for amplification and an internal sequence of random nucleotides, an inhibitor of non-sequence specific binding of DNA-binding proteins to the oligonucleotide duplexes and a sample containing a mixture of DNA-binding proteins; (b) separating unbound oligonucleotide duplexes from oligonucleotide duplexes complexed with the DNA-binding proteins on the basis of differences in physical or biochemical properties; (c) recovering the DNA-binding proteins from the complexes. Subsequent to step (b): the complexed duplexes are amplified, mixed with the sample containing DNA-binding proteins; and separated on the basis of differences in physical or biochemical properties; wherein the amplifying, mixing, and separating steps are performed one or more times. The sample is a nuclear extract, a cellular extract or intact nuclei. The internal sequence is a random 12 sequence, from about 6 to about 25 base pairs or is from about 8 to about 12 base pairs. The method of separation is based on differences in mobility, such as polyacrylamide gel electrophoresis or size-exclusion chromatography. In another embodiment Weissman discloses a method for simultaneously determining nucleotide recognition sequences for DNA-binding proteins, comprising the steps outlined above, further comprising analyzing the amplified duplexes to determine nucleotide recognition sequences for the

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DNA-binding proteins. The analyzing step comprises ligating the amplified duplexes to a vector to generate clones; and determining the DNA sequences of the cloned duplexes. The analyzing step comprises denaturing the amplified duplexes; hybridizing the denatured duplexes to an array of single-stranded oligonucleotides having different sequences; and detecting oligonucleotides hybridized with denatured duplexes. See further col. 4, line 12 as to the multiple selection technique up to col. 18, line 60, including the Examples. The Examples provide a detailed description of the method utilizing specific process steps with specific components. The specific process steps of Weissman therefore fully meet the claimed broad process of undefined components therein.

Double Patenting

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-71 of copending Application No. 09/877,243 ('243 application) or claims 1-31 of copending application No. 09/947,274 ('274 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the copending applications ('243 or '274) is an obvious variant of the instant

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application. For example, the '243 applications recites similar process steps as the instant application except the instant application recites for screening for a modulator of tf. The instant specification does not recite for any modulators but present similar, if not the same process steps of the '243 application. See the entire specification of the '243 application. The '274 application also relates to identifying a modulator of the tf as recited in claim 18, for example, albeit the preamble recites for identifying the protein in the sample.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

REASSIGNMENT OF LOCATION

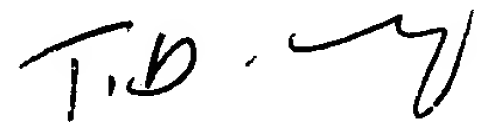
The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit **1639**.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
May 5, 2003